

REMARKS/ARGUMENTS

Claims 1, 2, 4 and 12-16 remain in the application. Claims 3, 5 and 6 are canceled.

Claims 7-11 were withdrawn.

Objection to Specification

The Examiner noted that the places where trademarks are used in the specification should also be accompanied by the generic terminology. Amendments to the specification are presented to correct the specification accordingly. No new matter has been added. Thus, Applicants respectfully submit that the objection to the specification is overcome and withdrawal thereof is requested.

Claim Rejections - 35 USC § 112, First Paragraph

The Examiner rejected claims 3 and 5 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants respectfully disagree.

Applicants respectfully submit that the specification of the present application is enabling because one reasonably skilled in the art could make or use the invention from the disclosures in the application coupled with information known in the art without undue experimentation. Applicants further submit that the currently amended claims narrow the scope of the claims and the rejection of claims 3 and 5 under 35 USC § 112, first paragraph is overcome. Withdrawal of the rejection thereof is requested.

Claim Rejections - 35 USC §112, Second Paragraph

under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the application regards as the invention. The claim has been amended to overcome this rejection and Applicants respectfully request that the rejection be withdrawn.

The Examiner rejected claims 1-6 and 14-16 under 35 U.S.C. 112, second paragraph, on the ground that the claim 1 is indefinite with regard to the phrase, "certain extent." In view of the amendments to claim 1 set forth above, the claim rejections are overcome and withdrawal thereof is respectfully requested.

The Examiner found claims 2-6 to be indefinite because of the phrase, "a modification of the T-cell population" whereby it is unclear whether there is a change in the number of specific T-cell type, or if there is a down regulation or an up regulation in the overall amount of T-cells. Applicants respectfully disagree. There is an up regulation in the overall amount of T-cells or more precisely a "normalization" in the overall amount of T-cells. Referring to page 17 of reference WO 00/62657, it states

"With increasing age there is a highly significant decrease in both thymus weight and total thymocyte number... The decrease in thymic weight can be attributed to a decrease in total thymocyte number... By removing the effects of sex steroids on the thymus by castration, regeneration occurs and by 4 weeks post-castration, the thymus is equivalent to that of the young adult in both weight and cellularity... Interestingly, there is a significant increase in thymocyte numbers at 2 weeks post-castration, which is restored to normal young levels by 4 weeks post-castration."

As explained in the description of the application it is not necessary to remain under the castration level to up regulate (or normalize) in the overall amount of T-cells. Such an up regulation (or normalization) is already possible with a smaller dosage of LHRH antagonists. That has a favorable effect on the mentioned side effects during the treatment. Applicants respectfully request that the rejection be withdrawn.

The Examiner found claims 14-16 to be indefinite because of the dosing regimen or interval is unclear. The claims has been amended to overcome this rejection and Applicants respectfully request that the rejection be withdrawn.

The Examiner also found claims 14-16 to be indefinite because the phrases “needs” and “as needed” is vague and requires further clarification. Similarly, these claims has been amended to overcome this rejection and Applicants respectfully request that the rejection be withdrawn.

Claim Rejections - 35 USC §102(b)

The Examiner has rejected claims 1-4 and 12-16 under 35 USC §102(b) as being anticipated by Engel *et al.* (WO 98/10781).

Under 35 USC §102, a claim can be rejected only if each element of the claim is disclosed in a single prior art reference. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the . . . claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Applicants respectfully submit that Engel *et al.* fails to teach or suggest, either expressly or inherently, each and every element of the claimed invention as amended.

The Examiner found that Engel *et al.* teaches a method for treating BPH and prostate cancer using the LHRH antagonist Cetrorelix, but it has no mention of the ability to modify T-cell populations. Furthermore, the Examiner found that Engel *et al.* teaches specific doses that anticipate the claimed doses and contained inherent properties that do

not need to be disclosed explicitly in order to meet all of the limitations of the claims of the present invention, such as the ability to modify T-cell populations. The Examiner has also rejected claims 1 and 2 under 35 USC §102(b) as being anticipated by Zakharova *et al.* whereby Zakharova *et al.* teach that LHRH antagonists can decrease thymocyte (T-cell) proliferation. However, the Applicants respectfully disagree with the Examiner's positions.

Manual of Patent Examining Procedure (MPEP) 2112 provides,

"The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). "

For the reasons discussed above, Applicants believe that the Examiner is speculative and conclusory in his rejections. However, Applicants have narrowed the Claim 4 to remove the indication of benign prostatic hyperplasia in view of the rejection. Applicants further

submit that these amended claims obviate the § 102(b) rejections and accordingly Applicants request withdrawal of these rejections.

Claim Rejections - 35 USC §103(a)

The Examiner has rejected claim 6 under 35 USC §103(a) as being unpatentable over Dubernard *et al.* in view of Zakharova *et al.* Applicants have canceled claim 6 and this rejection is now moot.

Statutory Double Patenting - 35 USC §101

The Examiner has also provisionally rejected claims 1-14 under a statutory obviousness-type double patenting rejection as claiming the same invention as that of claims 1-11 of copending Application No. 10/717,129. Applicants submit that the Application No. 10/717,129 is abandoned and the § 101 rejections is no longer relevant. Accordingly Applicants request withdrawal of the rejection as the claims are no longer coextensive in scope.

Conclusion

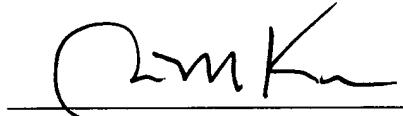
Based on the foregoing amendments and remarks, favorable consideration and allowance of all of the claims now present in the application are respectfully requested.

Should the Examiner require or consider it advisable that the specification, claims and/or drawings be further amended or corrected in formal respects in order to place the case in condition for final allowance, then it is respectfully requested that such amendment or correction be carried out by Examiner's Amendment and the case passed to issue.

Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing this case to allowance, the Examiner is invited to telephone the undersigned.

The Commissioner is authorized to charge any required fees, including any extension and/or excess claim fees, any additional fees, or credit any overpayment, to Goodwin Procter LLP Deposit Account No. 06-0923.

Respectfully submitted for Applicant,



Ann-Marie Koss, (Reg. No. 54,237)
GOODWIN PROCTER LLP
599 Lexington Avenue
New York, NY 10022
(212) 459-7434